designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(6) *Warning labels.* Except as provided in paragraph (c)(6)(iv) of this section, microwave ovens shall have the following warning labels:

(i) A label, permanently attached to or inscribed on the oven, which shall be legible and readily viewable during normal oven use, and which shall have the title emphasized and be so located as to elicit the attention of the user. The label shall bear the following warning statement:

PRECAUTIONS FOR SAFE USE TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY

DO NOT Attempt to Operate This Oven With:
(*a*) Object Caught in Door.
(*b*) Door That Does Not Close Properly.
(*c*) Damaged Door, Hinge, Latch, or Sealing Surface.

(ii) A label, permanently attached to or inscribed on the external surface of the oven, which shall be legible and readily viewable during servicing, and which shall have the word ''CAUTION'' emphasized and be so located as to elicit the attention of service personnel. The label shall bear the following warning statement:

CAUTION: This Device is to be Serviced Only by Properly Qualified Service Personnel. Consult the Service Manual for Proper Service Procedures to Assure Continued Compliance with the Federal Performance Standard for Microwave Ovens and for Precautions to be Taken to Avoid Possible Exposure to Excessive Microwave Energy.

(iii) The labels provided in accordance with paragraphs (c)(6)(i) and (ii) of this section shall bear only the statements specified in that paragraph, except for additional radiation safety warnings or instructions which may be necessary for particular oven designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(iv) Upon application by a manufacturer, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c)(1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(*a*) The specific microwave oven model(s) for which the exemption is sought.

(*b*) The specific radiation safety warning(s) from which exemption is sought.

(*c*) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(*d*) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

[38 FR 28640, Oct. 15, 1973, as amended at 40 FR 14752, Apr. 4, 1975; 40 FR 52007, Nov. 7, 1975; 46 FR 8461, Jan. 27, 1981; 48 FR 57482, Dec. 30, 1983; 50 FR 13566, Apr. 5, 1985; 53 FR 11254, Apr. 6, 1988; 59 FR 14365, Mar. 28, 1994]

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Sec.

AUTHORITY: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

§ 1040.10 Laser products.

(a) *Applicability.* The provisions of this section and § 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after August 1, 1976, except when:

(1) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:

(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002.

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31.

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) *Accessible emission level* means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible, as defined in paragraphs (b) (12), (15), and (22) of this section.

(2) *Accessible emission limit* means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) *Aperture* means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) *Aperture stop* means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) *Class I laser product* means any laser product that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in table I of paragraph (d) of this section.[1]

(6) *Class IIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table I, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table II-A of paragraph (d) of this section.[2]

(7) *Class II laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table II-A, but does not permit human access during operation to levels of

[1] Class I levels of laser radiation are not considered to be hazardous.

[2] Class IIa levels of laser radiation are not considered to be hazardous if viewed for any period of time less than or equal to 1×10^3 seconds but are considered to be a chronic viewing hazard for any period of time greater than 1×10^3 seconds.

laser radiation in excess of the accessible emission limits contained in table II of paragraph (d) of this section.[3]

(8) *Class IIIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table II, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-A of paragraph (d) of this section.[4]

(9) *Class IIIb laser product* means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of table III-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-B of paragraph (d) of this section.[5]

(10) *Class III laser product* means any Class IIIa or Class IIIb laser product.

(11) *Class IV laser product* means any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-B of paragraph (d) of this section.[6]

(12) *Collateral radiation* means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

(13) *Demonstration laser product* means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term ''demonstration laser product'' does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(14) *Emission duration* means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance, or service of a laser product.

(15) *Human access* means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class IIIb or IV levels of laser radiation, ''human access'' also means access to laser radiation that can be reflected directly by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.

(16) *Integrated radiance* means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($Jcm^{-2}\ sr^{-1}$).

(17) *Invisible radiation* means laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to 1.0×10^6 nm (1 millimeter).

(18) *Irradiance* means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter ($W\ cm^{-2}$).

(19) *Laser* means any device that can be made to produce or amplify electromagnetic radiation at wavelenghts greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at wavelengths equal to or greater than 180 nm but less than or equal to 1.0×10^6 nm primarily by the process of controlled stimulated emission.

(20) *Laser energy source* means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

[3] Class II levels of laser radiation are considered to be a chronic viewing hazard.

[4] Class IIIa levels of laser radiation are considered to be, depending upon the irradiance, either an acute intrabeam viewing hazard or chronic viewing hazard, and an acute viewing hazard if viewed directly with optical instruments.

[5] Class IIIb levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.

[6] Class IV levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.

(21) *Laser product* means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product.

(22) *Laser radiation* means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(19) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section.

(23) *Laser system* means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph (c)(2) of this section for an explanation of the term ''removable laser system.''

(24) *Maintenance* means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b) (27) and (38) of this section.

(25) *Maximum output* means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined under paragraph (e) of this section.

(26) *Medical laser product* means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended or promoted for in vivo laser irradiation of any part of the human body for the purpose of: (i) Diagnosis, surgery, or therapy; or (ii) relative positioning of the human body.

(27) *Operation* means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraphs (b) (24) and (38) of this section.

(28) *Protective housing* means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in §1040.11.

(29) *Pulse duration* means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(30) *Radiance* means time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($W\ cm^{-2}\ sr^{-1}$).

(31) *Radiant energy* means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(32) *Radiant exposure* means the radiant energy incident on an element of a surface divided by the area of the element, expressed in joules per square centimeter (Jcm^{-2})

(33) *Radiant power* means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).

(34) *Remote interlock connector* means an electrical connector which permits the connection of external remote interlocks.

(35) *Safety interlock* means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(36) *Sampling interval* means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (t).

(37) *Scanned laser radiation* means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(38) *Service* means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for

which this section and §1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b) (24) and (27) of this section.

(39) *Surveying, leveling, or alignment laser product* means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(40) *Visible radiation* means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 710 nm.

(41) *Warning logotype* means a logotype as illustrated in either figure 1 or figure 2 of paragraph (g) of this section.

(42) *Wavelength* means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser products*—(1) *All laser products.* Each laser product shall be classified in Class I, IIa, II, IIIa, IIIb, or IV in accordance with definitions set forth in paragraphs (b) (5) through (11) of this section. The product classification shall be based on the highest accessible emission level(s) of laser radiation to which human access is possible during operation in accordance with paragraphs (d), (e), and (f)(1) of this section.

(2) *Removable laser systems.* Any laser system that is incorporated into a laser product subject to the requirements of this section and that is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation in each class are specified in tables I, II-A, II, III-A, and III-B of this paragraph. The factors, k_1 and k_2 vary with wavelength and emission duration. These factors are given in table IV of this paragraph, with selected numerical values in table V of this paragraph. Accessible emission limits for collateral radiation are specified in table VI of this paragraph.

NOTES APPLICABLE TO TABLES I, II-A, II, III-A AND III-B: (1) The factors k_1 and k_2 are wavelength-dependent correction factors determined from table IV.

(2) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

TABLE I

CLASS I ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class I-Accessible emission limits (value)	(unit)	(quantity)**
≥180 but ≤400	≤3.0×10^{4}	$2.4 \times 10^{-5} k_1 k_2$*	Joules(J)*	radiant energy
	>3.0×10^{4}	$8.0 \times 10^{-10} k_1 k_2$*	Watts(W)*	radiant power
>400 but ≤1400	>1.0×10^{-9} to 2.0×10^{-5}	$2.0 \times 10^{-7} k_1 k_2$	J	radiant energy
	>2.0×10^{-5} to 1.0×10^{1}	$7.0 \times 10^{-4} k_1 k_2 t^{3/4}$	J	radiant energy
	>1.0×10^{1} to 1.0×10^{4}	$3.9 \times 10^{-3} k_1 k_2$	J	radiant energy
	>1.0×10^{4}	$3.9 \times 10^{-7} k_1 k_2$	W	radiant power
	and also (See paragraph (d)(4) of this section)			
	>1.0×10^{-9} to 1.0×10^{1}	$10 k_1 k_2 t^{1/3}$	$Jcm^{-2}sr^{-1}$	integrated radiance
	>1.0×10^{1} to 1.0×10^{4}	$20 k_1 k_2$	$Jcm^{-2}sr^{-1}$	integrated radiance
	>1.0×10^{4}	$2.0 \times 10^{-3} k_1 k_2$	$Wcm^{-2}sr^{-1}$	radiance
>1400 but ≤2500	>1.0×10^{-9} to 1.0×10^{-7}	$7.9 \times 10^{-5} k_1 k_2$	J	radiant energy
	>1.0×10^{-7} to 1.0×10^{1}	$4.4 \times 10^{-3} k_1 k_2 t^{1/4}$	J	radiant energy
	>1.0×10^{1}	$7.9 \times 10^{-4} k_1 k_2$	W	radiant power
>2500 but ≤1.0×10^{6}	>1.0×10^{-9} to 1.0×10^{-7}	$1.0 \times 10^{-2} k_1 k_2$	Jcm^{-2}	radiant exposure
	>1.0×10^{-7} to 1.0×10^{1}	$5.6 \times 10^{-1} k_1 k_2 t^{1/4}$	Jcm^{-2}	radiant exposure
	>1.0×10^{1}	$1.0 \times 10^{-1} k_1 k_2 t$	Jcm^{-2}	radiant exposure

*Class I accessible emission limits for wavelengths equal to or greater than 180 nm but less than or equal to 400 nm shall not exceed the Class I accessible emission limits for the wavelengths greater than 1400 nm but less than or equal to 1.0×10^{6} nm with a k_1 and k_2 of 1.0 for comparable sampling intervals.

**Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II-A

CLASS IIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class IIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>1.0 \times 10^{3}$	3.9×10^{-6}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II

CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS II ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class II-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>2.5 \times 10^{-1}$	1.0×10^{-3}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-A

CLASS IIIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class IIIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>3.8 \times 10^{-4}$	5.0×10^{-3}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-B

CLASS IIIb ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class IIIb-Accessible emission limits		
		(value)	(unit)	(quantity)*
≥180 but ≤400	$\leq 2.5 \times 10^{-1}$	$3.8 \times 10^{-4} k_1 k_2$	J	radiant energy
	$>2.5 \times 10^{-1}$	$1.5 \times 10^{-3} k_1 k_2$	W	radiant power
>400 but ≤1400	$>1.0 \times 10^{-9}$ to 2.5×10^{-1}	$10 k_1 k_2 t^{1/3}$ to a maximum value of 10	Jcm^{-2}	radiant exposure
			Jcm^{-2}	radiant exposure
	$>2.5 \times 10^{-1}$	5.0×10^{-1}	W	radiant power
>1400 but ≤1.0×10^6	$>1.0 \times 10^{-9}$ to 1.0×10^{1}	10	Jcm^{-2}	radiant exposure
	$>1.0 \times 10^{1}$	5.0×10^{-1}	W	radiant power

*Measurement parameter and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE IV

VALUES OF WAVELENGTH DEPENDENT CORRECTION FACTORS k_1 AND k_2

Wavelength (nanometers)	k_1	k_2		
180 to 302.4	1.0	1.0		
> 302.4 to 315	$10^{\left[\frac{\lambda - 302.4}{5}\right]}$	1.0		
> 315 to 400	330.0	1.0		
> 400 to 700	1.0	1.0		
> 700 to 800	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq \frac{10100}{\lambda - 699}$ then: $k_2 = 1.0$	if: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{t(\lambda - 699)}{10100}$	if: $t > 10^4$ then: $k_2 = \frac{\lambda - 699}{1.01}$
> 800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq 100$ then: $k_2 = 1.0$	if: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$	if: $t > 10^4$ then: $k_2 = 100$
> 1060 to 1400	5.0			
> 1400 to 1535	1.0	1.0		
> 1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$	1.0		
	$t > 10^{-7}$ $k_1 = 1.0$			
> 1545 to 1.0×10^6	1.0	1.0		

Note: The variables in the expressions are the magnitudes of the sampling interval(t), in units of seconds, and the wavelength (λ), in units of nanometers.

TABLE V

SELECTED NUMERICAL SOLUTIONS FOR k_1 AND k_2

Wavelength (nanometers)	k_1	k_2				
		$t \leq 100$	$t=300$	$t=1000$	$t=3000$	$t \geq 10{,}000$
180	1.0	1.0				
300	1.0					
302	1.0					
303	1.32					
304	2.09					
305	3.31					
306	5.25					
307	8.32					
308	13.2					
309	20.9					
310	33.1					
311	52.5					
312	83.2					
313	132.0					
314	209.0					
315	330.0					
400	330.0					
401	1.0					
500	1.0					
600	1.0					
700	1.0					
710	1.05	1	1	1.1	3.3	11.0
720	1.09	1	1	2.1	6.3	21.0
730	1.14	1	1	2.1	9.3	31.0
740	1.20	1	1.2	4.1	12.0	41.0
750	1.25	1	1.5	5.0	15.0	50.0
760	1.31	1	1.8	6.0	18.0	60.0
770	1.37	1	2.1	7.0	21.0	70.0
780	1.43	1	2.4	8.0	24.0	80.0
790	1.50	1	2.7	9.0	27.0	90.0
800	1.56	1	3.0	10.0	30.0	100.0
850	1.95	1	3.0	10.0	30.0	100.0
900	2.44	1	3.0	10.0	30.0	100.0
950	3.05	1	3.0	10.0	30.0	100.0
1000	3.82	1	3.0	10.0	30.0	100.0
1050	4.78	1	3.0	10.0	30.0	100.0
1060	5.00	1	3.0	10.0	30.0	100.0
1100	5.00	1	3.0	10.0	30.0	100.0
1400	5.00	1	3.0	10.0	30.0	100.0
1500	1.0	1.0				
1540	100.0*					
1600	1.0					
$1.0X10^6$	1.0					

* The factor $k_1 = 100.0$ when $t \leq 10^{-7}$, and $k_1 = 1.0$ when $t > 10^{-7}$

Note: The variable (t) is the magnitude of the sampling interval in units of seconds.

TABLE VI

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL

RADIATION FROM LASER PRODUCTS

1. Accessible emission limits for collateral radiation having wavelengths greater than 180 nanometers but less than or equal to 1.0×10^{6} nanometers are identical to the accessible emission limits of Class I laser radiation, as determined from Tables I and IV in this paragraph.
i. In the wavelength range of less than or equal to 400 nanometers, for all emission durations;
ii. In the wavelength range of greater than 400 nanometers, for all emission durations less than or equal to 1×10^{3} seconds and, when applicable under paragraph (f)(8) of this section, for all emission durations.
2. Accessible emission limit for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.

(1) *Beam of a single wavelength.* Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in tables I, II-A, II, III-A, and III-B of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d) (1) or (2) of this section.

(4) *Class I dual limits.* Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1.400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in table I of this paragraph, and

(ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in table I of this paragraph.

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification under §1010.2 is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Except as provided in §1010.13, tests for compliance with each of the applicable requirements of this section and §1040.11 shall be made during operation, maintenance, or service as appropriate:

(i) Under those conditions and procedures which maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and

(iii) At points in space to which human access is possible in the product configuration which is necessary to determine compliance with each requirement, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and

(v) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less. For scanned laser radiation, the direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle stated above shall be used for all other laser products (except that a 7 millimeter diameter aperture stop shall be used in the measurement of scanned laser radiation emitted by laser products manufactured on or before August 20, 1986.

(ii) The irradiance (W cm^{-2}) or radiant exposure (J cm^{-2} equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of $1 \times \times 10^{-3}$ steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^{-2}).

(iii) The radiance (W cm^{-2} sr^{-1}) or integrated radiance (J cm^{-2} sr^{-1}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^{-2}).

(f) *Performance requirements*—(1) *Protective housing.* Each laser product shall have a protective housing that prevents human access during operation

to laser and collateral radiation that exceed the limits of Class I and table VI, respectively, wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class I is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.

(2) *Safety interlocks.* (i) Each laser product, regardless of its class, shall be provided with at least one safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s), human access to laser or collateral radiation in excess of the accessible emission limit applicable under paragraph (f)(1) of this section.

(ii) Each required safety interlock, unless defeated, shall prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing

(iii) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided, if failure of a single interlock would allow;

(*a*) Human access to a level of laser radiation in excess of the accessible emission limits of Class IIIa; or

(*b*) Laser radiation in excess of the accessible emission limits of Class II to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(iv) Laser products that incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) *Remote interlock connector.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a readily available remote interlock connector having an electrical potential difference of no greater than 130 root-mean-square volts between terminals. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and table VI shall be prevented.

(4) *Key control.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator.* (i) Each laser system classified as a Class II or IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(ii) Each laser system classified as a Class IIIb or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(iii) For laser systems manufactured on or before August 20, 1986, if the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section. For laser systems manufactured after August 20, 1986, each separately housed laser and operation control of a laser system that regulates the laser or collateral radiation emitted by a product during operation shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section, if the laser or operation control can be operated at a separation distance greater than 2 meters from

any other separately housed portion of the laser product incorporating an emission indicator.

(iv) Any visible signal required by paragraph (f)(5) (i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(v) Emission indicators required by paragraph (f)(5) (i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI.

(6) *Beam attenuator.* (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and table VI.

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) *Location of controls.* Each Class IIa, II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI is unnecessary for operation or adjustment of such controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens during operation or maintenance to less than the accessible emission limits of Class I and table VI. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class I and table VI whenever the shutter is opened or the attenuator varied.

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI.

(9) *Scanning safeguard.* Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of:

(i) The accessible emission limits of the class of the product, or

(ii) The accessible emission limits of the class of the scanned laser radiation if the product is Class IIIb or IV and the accessible emission limits of Class IIIa would be exceeded solely as result of such failure.

(10) *Manual reset mechanism.* Each laser system manufactured after August 20, 1986, and classified as a Class IV laser product shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(g) *Labeling requirements.* In addition to the requirements of §§1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class IIa and II designations and warnings.* (i) Each Class IIa laser product shall have affixed a label bearing the following wording: ''Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation.''

(ii) Each Class II laser product shall have affixed a label bearing the warning logotype A (figure 1 in this paragraph) and including the following wording:

[Position I on the logotype]

''LASER RADIATION—DO NOT STARE INTO BEAM''; and

[Position 3 on the logotype]

''CLASS II LASER PRODUCT''.

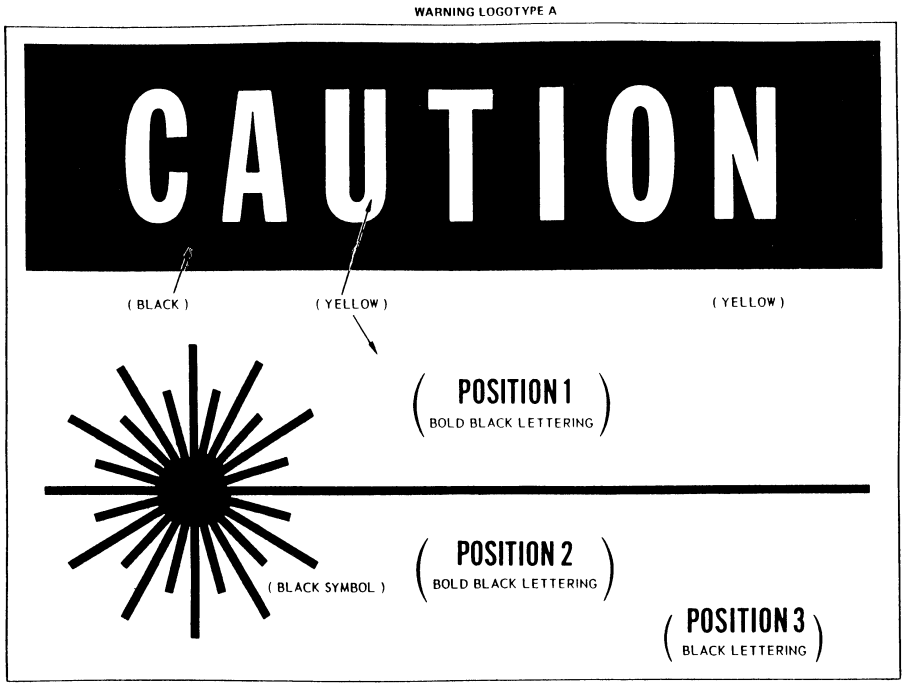

FIGURE 1

(2) *Class IIIa and IIIb designations and warnings.* (i) Each Class IIIa laser product with an irradiance less than or equal to 2.5×10^{-3} W cm^{2-} shall have affixed a label bearing the warning logotype A (figure 1 of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS''; and,

[Position 3 on the logotype]

''CLASS IIIa LASER PRODUCT''.

(ii) Each Class IIIa laser product with an irradiance greater than 2.5×10^{-3} W cm^{-2} shall have affixed a label bearing the warning logotype B (figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION—AVOID DIRECT EYE EXPOSURE''; and,

[Position 3 on the logotype]

''CLASS IIIa LASER PRODUCT''.

WARNING LOGOTYPE B

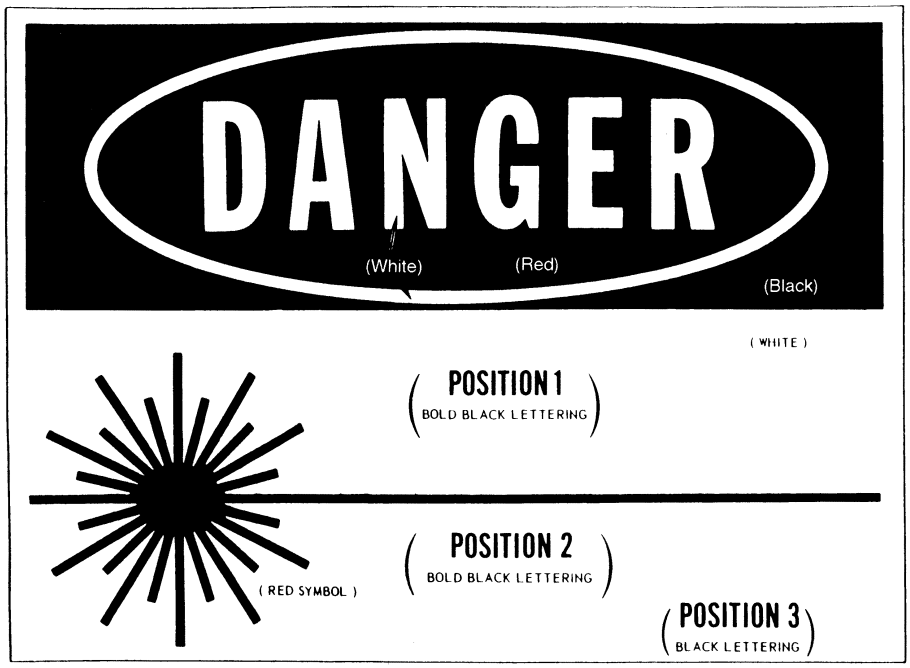

FIGURE 2

(iii) Each Class IIIb laser product shall have affixed a label bearing the warning logotype B (figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION—AVOID DIRECT EXPOSURE TO BEAM''; and,

[Position 3 on the logotype]

''CLASS IIIb LASER PRODUCT''.

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (figure 2 of paragraph (g)(2)(ii) of this section), and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION''; and,

[Position 3 on the logotype]

''CLASS IV LASER PRODUCT''.

(4) *Radiation output information on warning logotype.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) *Aperture label.* Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable.

(i) ''AVOID EXPOSURE—Laser radiation is emitted from this aperture,'' if the radiation emitted through such aperture is laser radiation.

(ii) ''AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture,'' if the radiation emitted through such aperture is collateral radiation described in table VI, item 1.

(iii) ''AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture,'' if the radiation emitted through such aperture is collateral radiation described in table VI, item 2.

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and table VI. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) ''CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM.'' for Class II accessible laser radiation.

(ii) ''CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.'' for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W $cm^{-2.}$

(iii) ''DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE.'' for Class IIIa accessible laser radiation with an irradiance greater than 2.5×10^{-3} W $cm^{-2.}$

(iv) ''DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM.'' for Class IIIb accessible laser radiation.

(v) ''DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.'' for Class IV accessible laser radiation.

(vi) ''CAUTION—Hazardous electromagnetic radiation when open.'' for collateral radiation in excess of the accessible emission limits in table VI, item 1 of paragraph (d) of this section.

(vii) ''CAUTION—Hazardous x-rays when open.'' for collateral radiation in excess of the accessible emission limits in table VI, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or table VI. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) ''CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM.'' for Class II accessible laser radiation.

(ii) ''CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.'' for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W $cm^{-2.}$

(iii) ''DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE.'' for Class IIIa accessible laser radiation when an irradiance greater than 2.5×10^{-3} W $cm^{-2.}$

(iv) ''DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM.'' for Class IIIb accessible laser radiation.

(v) ''DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.'' for Clas IV accessible laser radiation.

(vi) ''CAUTION—Hazardous electromagnetic radiation when open and interlock defeated.'' for collateral radiation in excess of the accessible emission limits in table VI. item 1 of paragraph (d) of this section.

(vii) ''CAUTION—Hazardous x-rays when open and interlock defeated.'' for collateral radiation in excess of the accesible emission limits in table VI. item 2 of paragraph (d) of this section.

(8) *Warning for visible and/or invisible radiation.* On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word ''invisible'' shall appropriately precede the word ''radiation''; or

(ii) Visible and invisible radiation, the words ''visible and invisible'' or ''visible and/or invisible'' shall appropriately precede the word ''radiation.''

(iii) Visible laser radiation only, the phrase ''laser light'' may replace the phrase ''laser radiation.''

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class I radiation or the limits of collateral radiation established to table VI of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and §1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and §1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in table I of paragraph (d) of this section determined under paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and §1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning ''Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.''

(v) In the case of laser products other than laser systems, a statment of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and §1040.11.

(vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher classification of the product, the following warning

shall be included in the user information: ''CAUTION—The use of optical instruments with this product will increase eye hazard.''

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and §1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified under §1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and §1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§1010.2. and 1010.3.

(The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910–0176)

[50 FR 33688, Aug. 20, 1985; 50 FR 42156, Oct. 18, 1985; 65 FR 17138, Mar. 31, 2000, as amended at 75 FR 20917, Apr. 22, 2010]

§1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of §1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) Incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body. Such means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section. Indication of the measurement shall be in International System Units. The requirements of this paragraph do not apply to any laser radiation that is all of the following:

(i) Of a level less than the accessible limits of Class IIIa; and

(ii) Used for relative positioning of the human body; and

(iii) Not used for irradiation of the human eye for ophthalmic purposes.

(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a)(1) of this section.

(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, a label bearing the wording: ''Laser aperture.''

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling. or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

[50 FR 33702, Aug. 20, 1985]

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Applicability.* (1) The provisions of this section, as amended, are applicable as specified herein to the following products manufactured on or after September 8, 1986.

(i) Any sunlamp product.

(ii) Any ultraviolet lamp intended for use in any sunlamp product.

(2) Sunlamp products and ultraviolet lamps manufactured on or after May 7, 1980, but before September 8, 1986, are subject to the provisions of this section as published in the FEDERAL REGISTER of November 9, 1979 (44 FR 65357).

(b) *Definitions.* As used in this section the following definitions apply:

(1) *Exposure position* means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.

(2) *Intended* means the same as ''intended uses'' in § 801.4.

(3) *Irradiance* means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm^2).

(4) *Maximum exposure time* means the greatest continuous exposure time interval recommended by the manufacturer of the product.

(5) *Maximum timer interval* means the greatest time interval setting on the timer of a product.

(6) *Protective eyewear* means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

(7) *Spectral irradiance* means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).

(8) *Spectral transmittance* means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

(9) *Sunlamp product* means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

(10) *Timer* means any device incorporated into a product that terminates radiation emission after a preset time interval.

(11) *Ultraviolet lamp* means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

(c) *Performance requirements*—(1) *Irradiance ratio limits.* For each sunlamp product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 200 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers may not exceed 0.003 at any distance and direction from the product or lamp.

(2) *Timer system.* (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval(s) may not exceed the manufacturer's

recommended maximum exposure time(s) that is indicated on the label required by paragraph (d)(1)(iv) of this section.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the sunlamp product has been terminated.

(v) The timer requirements do not preclude a product from allowing a user to reset the timer before the end of the preset time interval.

(3) *Control for termination of radiation emission.* Each sunlamp product shall incorporate a control on the product to enable the person being exposed to terminate manually radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp.

(4) *Protective eyewear.* (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of the protective eyewear required by paragraph (c)(4)(i) of this section shall not exceed a value of 0.001 over the wavelength range of greater than 200 nanometers 320 nanometers and a value of 0.01 over the wavelength range of greater than 320 nanometers through 400 nanometers, and shall be sufficient over the wavelength greater than 400 nanometers to enable the user to see clearly enough to reset the timer.

(5) *Compatibility of lamps.* An ultraviolet lamp may not be capable of insertion and operation in either the ''single-contact medium screw'' or the ''double-contact medium screw'' lampholders described in American National Standard C81.10–1976, Specifications for Electric Lamp Bases and Holders—Screw-Shell Types, which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(d) *Label requirements.* In addition to the labeling requirements in part 801 and the certification and identification requirements of §§1010.2 and 1010.3, each sunlamp product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) *Labels for sunlamp products.* Each sunlamp product shall have a label(s) which contains:

(i) A warning statement with the words ''DANGER—Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.''

(ii) Recommended exposure position(s). Any exposure position may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) A recommended exposure schedule including duration and spacing of sequential exposures and maximum exposure time(s) in minutes.

(v) A statement of the time it may take before the expected results appear.

(vi) Designation of the ultraviolet lamp type to be used in the product.

(2) *Labels for ultraviolet lamps.* Each ultraviolet lamp shall have a label which contains:

(i) The words ''Sunlamp—DANGER—Ultraviolet radiation. Follow instructions.''

(ii) The model identification.

(iii) The words ''Use ONLY in fixture equipped with a timer.''

(3) *Label specifications.* (i) Any label prescribed in this paragraph for sunlamp products shall be permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product.

(ii) Any label prescribed in this paragraph for ultraviolet lamps shall be permanently affixed or inscribed on the product so as to be legible and readily accessible to view.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, rm. 4312, Silver Spring, MD 20993–0002, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§1010.2(b) and 1010.3(a), the manfacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular; e.g., if they do not diminish the impact of the required statements; and are not prohibited by this chapter.

(e) *Instructions to be provided to users.* Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to avoid or to minimize potential injury to the user, including the following technical and safety information as applicable:

(1) *Sunlamp products.* The users' instructions for a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for determining the correct exposure time and schedule for persons according to skin type.

(v) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including

compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

(2) *Ultraviolet lamps.* The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraphs (d)(1)(i) and (2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

(iii) A clear identification by brand and model designation of all lamp models for which replacement lamps are promoted, if applicable.

(f) *Test for determination of compliance.* Tests on which certification pursuant to §1010.2 is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument.

[50 FR 36550, Sept. 6, 1985, as amended at 67 FR 9587, Mar. 4, 2002; 69 FR 18803, Apr. 9, 2004; 75 FR 20917, Apr. 22, 2010]

§ 1040.30 High-intensity mercury vapor discharge lamps.

(a) *Applicability.* The provisions of this section apply to any high-intensity mercury vapor discharge lamp that is designed, intended, or promoted for illumination purposes and is manufactured or assembled after March 7, 1980, except as described in paragraph (d)(1)(ii) of this section.

(b) *Definitions.* (1) *High-intensity mercury vapor discharge lamp* means any lamp including any ''mercury vapor'' and ''metal halide'' lamp, with the exception of the tungsten filament self-ballasted mercury vapor lamp, incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope.

(2) *Advertisement* means any catalog, specification sheet, price list, and any other descriptive or commercial brochure and literature, including videotape and film, pertaining to high-intensity mercury vapor discharge lamps.

(3) *Packaging* means any lamp carton, outer wrapping, or other means of containment that is intended for the storage, shipment, or display of a high-intensity mercury vapor lamp and is intended to identify the contents or recommend its use.

(4) *Outer envelope* means the lamp element, usually glass, surrounding a high-pressure arc discharge tube, that, when intact, attenuates the emission of shortwave ultraviolet radiation.

(5) *Shortwave ultraviolet radiation* means ultraviolet radiation with wavelengths shorter than 320 nanometers.

(6) *Cumulative operating time* means the sum of the times during which electric current passes through the high-pressure arc discharge.

(7) *Self-extinguishing lamp* means a high-intensity mercury vapor discharge lamp that is intended to comply with the requirements of paragraph (d)(1) of this section as applicable.

(8) *Reference ballast* is an inductive reactor designed to have the operating characteristics as listed in Section 7 in the American National Standard Specifications for High-Intensity Discharge Lamp Reference Ballasts (ANSI C82.5–1977)[1] or its equivalent.

(c) *General requirements for all lamps.* (1) Each high-intensity mercury vapor discharge lamp shall:

(i) Meet the requirements of either paragraph (d) or paragraph (e) of this section; and

(ii) Be permanently labeled or marked in such a manner that the name of the manufacturer and the month and year of manufacture of the lamp can be determined on an intact lamp and after the outer envelope of the lamp is broken or removed. The name of the manufacturer and month

[1] Copies are available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

and year of manufacture may be expressed in code or symbols, provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health, with the key to the code or symbols and the location of the coded information or symbols on the lamp.

(2) In lieu of permanently affixing or inscribing tags or labels on the product as required by §§1010.2(b) and 1010.3(a) of this chapter, the manufacturer of any high-intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

(d) *Requirements for self-extinguishing lamps*—(1) *Maximum cumulative operating time.* (i) Each self-extinguishing lamp manufactured after March 7, 1980 shall cease operation within a cumulative operating time not to exceed 15 minutes following complete breakage or removal of the outer envelope (with the exception of fragments extending 50 millimeters or less from the base shell); and

(ii) Each self-extinguishing lamp manufactured after September 7, 1981, shall cease operation within a cumulative operating time not to exceed 15 minutes following breakage or removal of at least 3 square centimeters of contiguous surface of the outer envelope.

(2) *Lamp labeling.* Each self-extinguishing lamp shall be clearly marked with the letter ''T'' on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.

(3) *Lamp packaging.* Lamp packaging for each self-extinguishing lamp shall clearly and prominently display:

(i) The letter ''T''; and

(ii) The words ''This lamp should self-extinguish within 15 minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation.''

(e) *Requirements for lamps that are not self-extinguishing lamps*—(1) *Lamp labeling.* Any high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall be clearly and legibly marked with the letter ''R'' on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.

(2) *Lamp packaging.* Lamp packaging for each high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall clearly and prominently display:

(i) The letter ''R''; and

(ii) The words ''WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available.''

(3) *Lamp advertisement.* Advertising for any high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall prominently display the following wording: ''WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available.''

(f) *Test conditions.* Any high-intensity mercury vapor discharge lamp under test for compliance with the requirements set forth in paragraph (d)(1) of this section shall be started and operated under the following conditions as applicable:

(1) Lamp voltage, current, and orientation shall be those indicated or recommended by the manufacturer for operation of the intact lamp.

(2) The lamp shall be operated on a reference ballast.

(3) The lamp shall be started in air that has a temperature of 25 ±5 °C. Heating and movement of the air surrounding the lamp shall be that produced by the lamp and ballast alone.

(4) If any test is performed in an enclosure, the enclosure shall be not less than 0.227 cubic meter (8 cubic feet).

(5) Any lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer supplies or specifies shall be tested in that fixture or luminaire. Any other lamp shall be tested with no reflector or other surrounding material.

[44 FR 52195, Sept. 7, 1979, as amended at 53 FR 11254, Apr. 6, 1988]

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

AUTHORITY: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

§ 1050.10 Ultrasonic therapy products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) *Definitions.* The following definitions apply to words and phrases used in this section:

(1) *Amplitude modulated waveform* means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) *Applicator* means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) *Beam cross-section* means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) *Beam nonuniformity ratio* means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) *Centroid of a surface* means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) *Collimating applicator* means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12 centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) *Continuous-wave waveform* means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) *Diverging applicator* means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b) (6) and (15) of this section.

(9) *Effective intensity* means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter ($W\ cm^{-2}$).

(10) *Effective radiating area* means the area consisting of all points of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) *Effective radiating surface* means the surface consisting of all points 5 millimeters from the applicator face.

(12) *Focal area* means the area of the focal surface, expressed in square centimeters (cm^2).

(13) *Focal length* means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) *Focal surface* means the beam cross-section with smallest area of a focusing applicator.

(15) *Focusing applicator* means an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half.

(16) *Generator* means that portion of a fully assembled ultrasonic therapy